K042837

NOV - 2 2004

Summary of Safety and Effectiveness
Liquichek Elevated CRP Control

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

October 12, 2004

2.0 Device Identification

Product Trade Name:	Liquichek Elevated CRP Control
Common Name:	Single (specified) analyte controls (assayed and unassayed)
Classifications:	Class I
Product Code:	JJX
Regulation Number:	21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Lipids Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K012513

4.0 Description of Device

Liquichek Elevated CRP Control is prepared from human serum with added constituents of human and animal origin, stabilizers, and preservatives. This product is provided in liquid form.

5.0 Intended Use

Liquichek Elevated CRP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for C-Reactive Protein (CRP).

6.0 Comparison of the new device with the Predicate Device

Liquichek Elevated CRP Control claims substantial equivalence to the Liquichek Lipids Control currently in commercial distribution (K012513). Both of these are liquid, human serum based controls. Liquichek Elevated CRP Control contains only CRP and Liquichek Lipids Control is a multi-analyte control.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	**Bio-Rad Laboratories** Liquichek™ Elevated CRP Control (New Device)	**Bio-Rad Laboratories** Liquichek™ Lipids Control (Predicate Device K012513)
Similarities		
Intended Use	Liquichek Elevated CRP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for C-Reactive Protein (CRP).	Liquichek Lipids Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Preservatives	Contains preservatives	Contains preservatives
Differences		
Storage (Unopened)	-10 to -70°C Until expiration date	–10°C to –20°C Until expiration date
Open Vial Claim	30 days at 2°C to 8 °C	14 days at 2 to 8°C
Analytes	Contains: ▪ C-Reactive Protein (CRP) Does not Contain: ▪ Apolipoprotein A-1 ▪ Apolipoprotein B ▪ Cholesterol ▪ Cholesterol HDL ▪ Cholesterol LDL ▪ Lipoprotein (a) ▪ Triglycerides	Contains: ▪ Apolipoprotein A-1 ▪ Apolipoprotein B ▪ Cholesterol ▪ Cholesterol HDL ▪ Cholesterol LDL ▪ C-Reactive Protein (CRP) ▪ Lipoprotein (a) ▪ Triglycerides

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Elevated CRP Control. Product claims are as follows:

7.1 **Open vial** 30 days at 2°C to 8 °C

7.2 **Shelf Life Stability** 3 Years at -10 to -70°C

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 2 2004

Ms. Elizabeth Platt
Quality Assurance/Regulatory Affairs Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k042837
Trade/Device Name: Liquichek Elevated CRP Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: October 11, 2004
Received: October 14, 2004

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042837

Device Name: **Liquichek Elevated CRP Control**

Indications For Use: **Liquichek Elevated CRP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for C-Reactive Protein (CRP).**

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042837